

RECOGNIZED COMPONENT Constructional Data Report (CDR)

1.0 Reference and Address									
Report Number	140800196SHA-001 Original Issued: 19-Aug-2014 Revised: None								
Standard(s)	ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Amendment 1; CAN/CSA-C22.2 No. 60601-1:14, Third Edition Issued: 2014/03/01 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.								
Applicant	GlobTek, Inc.	Manufacturer	GlobTek (Suzhou) Co., Ltd.						
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2.0 Product Description ITE/Medical Power Supply **Product** GlobTek Brand name The power supply is a switch mode power supply for building in. The unit has universal input (AC or DC) with active power factor correction. Factory configurable output is from 12 V to 55 V in 0.1 V increments. The unit have built in EMI filter, there is also remote output sensing options. Unit is provided as open frame power supply or as power supply unit with performed enclosure. Power supply unit can be provided with or without PE (Protective Earthing). Perforated enclosure with PE: Bottom metal plate is connected to protective earthing. Bottom metal plate is separated from primary circuit by basic insulation. Faston blade terminal used for connection of the protective earthing. PCB is connected to metal bottom plate by four screws (2) on primary side and 2 on secondary side). Primary screws provide protective earthing of the bottom metal plate. Additional insulation foil provided between PCB and bottom metal plate. Power supply unit was evaluated only for Means of Operator Protection. The equipment has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 2000m. The product with 50% output power was evaluated for a maximum ambient temperature of 70℃ for AC input voltage with 20 CFM airflow cooling. The product with 50% output power was evaluated for a maximum ambient temperature of 55°C for DC input voltage with 20 CFM airflow cooling. The product with 50% output power was evaluated for a maximum ambient temperature of 55℃ for AC input voltage with air convention co oling. The product with 50% output power was evaluated for a maximum ambient temperature of 50℃ for DC input voltage with air convention Description cooling. The product with 100% output power was evaluated for a maximum ambient temperature of 40°C for AC and DC input voltage with air convention cooling. The temperature test was performed 100 mm above bench. Perforated enclosure without PE: The following capacitors shall be removed from the equipment (CY1, CY2, CY3, CY4, CY5, CY6 and CY7). Connecting wire between internal primary parts (marked with "B") shall be also removed from the equipment. Metal bottom plate is separated from primary circuit by reinforced insulation; there is also reinforced insulation between primary and secondary circuit. Additional insulation foil provided between PCB and bottom metal plate not protectively earthed. Open-frame power supply unit with PE: Faston blade terminal used for connection of the protective earthing. PCB shall be secured within the end product by four screws. Spacers provided between PCB of the power supply unit and end product plate (length of 10 mm). Shorten than 10,0 mm spacers are allowed when a plastic insulator, min. 0.4 mm thickness and with dielectric withstand voltage rating of min. 4000 Vac, is provided between the bottom side of the power supply unit and the system plate or chassis. Open-frame power supply unit without PE: PCB shall be secured within the end product by four screws. Spacers provided between PCB of the power supply unit and end product plate (length of 10 mm). Shorten than 10.0 mm spacers are allowed when a plastic insulator, min. 0,4 mm thickness and with dielectric withstand voltage rating of min. 4000 Vac, is provided between the bottom side of the power supply unit and the system plate or chassis. In the unit, there is single output plus fan voltage for 20 CFM airflow (External Fan is optional used).

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2.0 Product Description GT*91110P240*-****-* (The 1st "*" part can be 'M' or '-' or 'H'; The 2nd "*" part can be "12", "15", " 18", "24", "36", "48" or "55"; The 3rd "*" part can be 'F' or 'C'; The 4th "*" part can be 'A' or blank; The 5th "*" part can be "W" or blank; The 6th "*" part can be "-0.1" to "-11.9" with interval of 0.1 or Models blank; The 7th "*" part can be 'S' or "HIOXXX" or "HOXXX" or "HIXXX". "XXX" can be from 000 to 500 with interval of 1.) GT*91110P240*-***-* The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety. The 2nd "*" part denotes the standard rated output voltage designation, which can be "12", "15", " 18", "24", "36", "48" or "55". The 3rd "*" part can be 'F' which means open frame or 'C' which means perforated enclosure. The 4th "*" part can be 'A' which means airflow for 240 W load or blank which means no airflow. The 5th "*" part can be 'W' which means Class II or blank which means Class I. Model The 6th "*" part is optional, which can be "-0.1" to "-11.9" with interval of 0.1 to denote voltage Similarity deviation or blank to indicate no voltage different. The result by subtracting the deviation value from the standard rated output voltage denotes the rated output voltage. The 7th "*" part can be 'S' or "HIOXXX" or "HOXXX" or "HIXXX". S = Input header and output header connectors on board HIOXXX = Input and output wire harness. Where XXX can be from 000 to 500 to indicate harness length (maximum length for input and output harnesses is 500mm). HOXXX = Input header connector on board and output wire harness. Where XXX can be from 000 to 500 to indicate harness length (maximum harness length for output is 500 mm). HIXXX = Input wire harness. Output header on board. Where XXX can be from 000 to 500 to indicate harness length (maximum harness length for input is 500mm). Input: 100-240 Vac, 50-60 Hz, 4.0A or 130-320 Vdc, 2.5 A Ratings Output: Refer to illustration No.1 for details. Other Ratings N/A

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2.0 Product Description

The products covered in this Report are incomplete in construction features or limited in performance capabilities and are intended for use and evaluation in other products. Consideration should be given to the following when the component is used in or with another

- 1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:
- 60601-1 Clause 7.5 (Safety Signs),
- 60601-1 Clause 7.9 (Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.),
- 60601-1 Clause 8.11.5 (Mains Fuse with High Breaking Capacity),
- 60601-1 Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- 60601-1 Clause 10 (Radiation),
- 60601-1 Clause 11.7 (Biocompatibility),
- 60601-1 Clause 14 (PEMS),
- 60601-1 Clause 15 (Construction),
- 60601-1 Clause 16 (ME Systems)
- 60601-1 Clause 17 (EMC),
- 60601-1 Risk Management was excluded from this investigation.
- For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.

Conditions of Acceptability

- For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1/F2).
- For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.
- For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.
- For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.

3.0 Product Photographs

Photo 1 - External view - 1 of EUT with perforated enclosure

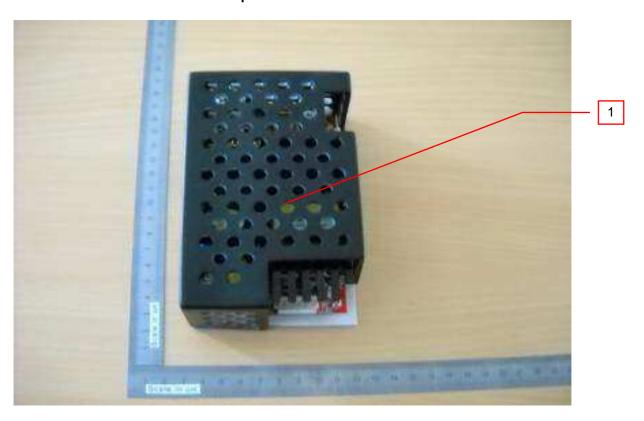


Photo 2 - Bottom view of EUT with perforated enclosure

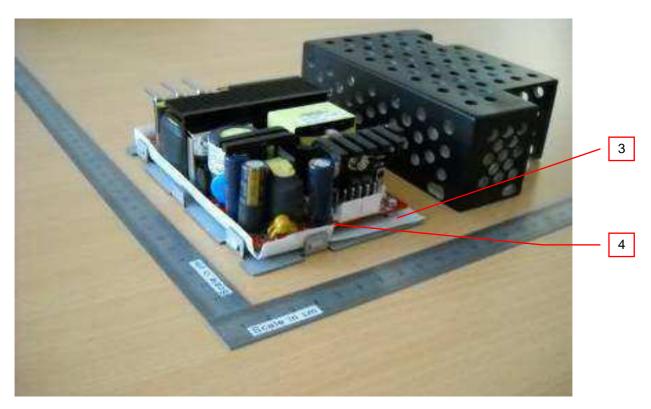


3.0 Product Photographs

Photo 3 - External view - 2 of EUT with perforated enclosure



Photo 4 - Internal view of EUT with perforated enclosure



3.0 Product Photographs

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Photo 5 - External view of EUT (open frame model)

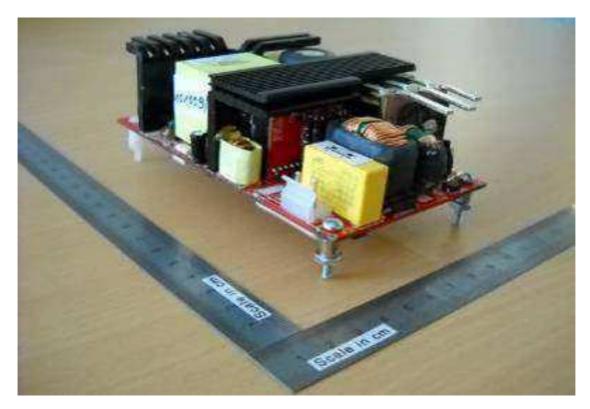
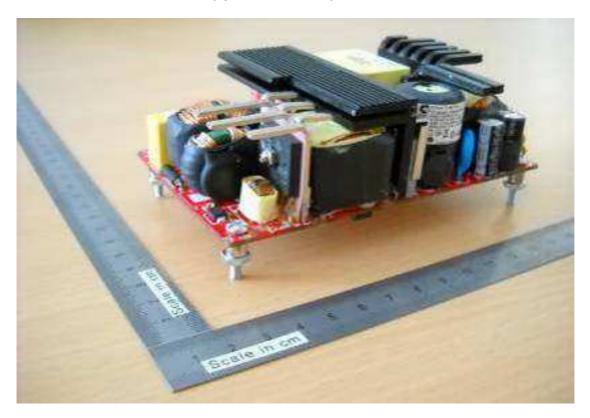


Photo 6 - External view - 2 of EUT (open frame model)



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3.0 Product Photographs

Photo 7 - Component side view of PCB

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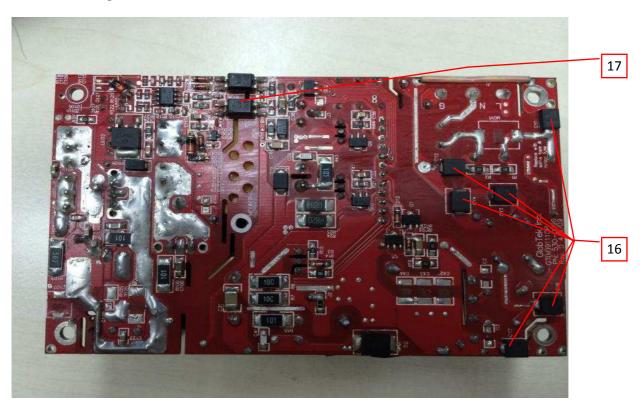
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Photo 8 - Soldering side view of PCB



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3.0 Product Photographs

Photo 9 - Lateral view - 1 of PCB

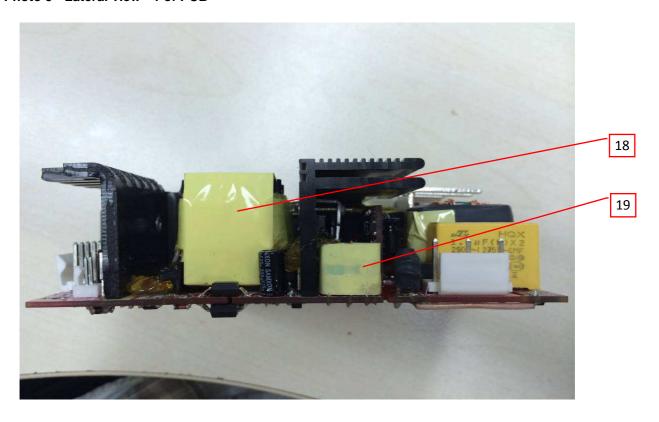
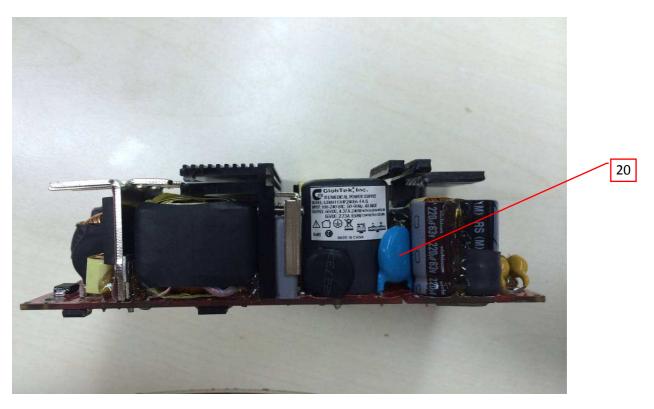


Photo 10 - Lateral view - 2 of PCB



4.0 (Critica	al Components				
Photo #	Item no.1	Name	Manufacturer/ trademark ²	Type / model ²	Technical data and securement means	Mark(s) of conformity ³
		Plastic enclosure	SABIC INNOVATIVE PLASTICS B V	SE1 SE1X SE100X SE100	Min. V-1 at 1.5 mm thickness	
1	1 for performed enclosure model	SABIC INNOVATIVE PLASTICS B V	HF500R C2950	Min. V-0 at 1.5 mm thickness	cURus	
			SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	Min. V-1 at 1.25 mm thickness	
3	2	Bottom enclosure for performed enclosure model	Various	Various	Thickness 0.6 mm, metal plated	NR
			FORMEX, DIV OF ILLINOIS TOOL WORKS INC, FORMERLY	FORMEX GK	V-0, 115℃, min, 0.4 mm thickness	
			SKC CO LTD	SH71S	VTM-2, min. 0.4 mm thickness, min. 105℃	
			TORAY INDUSTRIES INC	Lumirror H10	VTM-2, min. 0.4 mm thickness, min. 105℃	
5	3	Insulation sheet for performed enclosure model	SABIC INNOVATIVE PLASTICS US L L C	FR60 series FR63 series FR65 series FR7 series FR700 series	V-0, min. 0.4 mm thickness, min. 130℃	cURus
			MIANYANG LONGHUA FILM CO LTD	PP-BK-20 PP-BK-17 PP-BK-18	VTM-0, min. 0.4 mm thickness, min. 80℃	
			ITW ELECTRONICS COMPONENTS/ PRODUCTS (SHANGHAI) CO LTD	FORMEX-18 FORMEX-17	V-0, min. 0.4 mm thickness, min. 100℃	
			SUZHOU XINKE ELECTRONICS CO LTD	XK-2		
5	4	PCB material	SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD	тсх	Min. 1.7 mm thickness, min. V- 0, 130℃	cURus
			SHANGHAI AREX PRECISION ELECTRONIC CO LTD	04V0 02V0		
5	5	Bonding wire for Class I model	Various Various	Various 1185 1015	Min.300V, min.105℃, min.18 AWG	cURus
		(Not shown)	WALTER	1007 TAP	T5A, 250V, Rated breaking	
7	6	Fuse (F1) (Not	ELECTRONIC CO LTD	ICP series	capacity 50A	cURus
		shown)	CONQUER ELECTRONICS CO LTD	PTP	T5A, 250V, Rated breaking capacity 50A	

4.0 Critical Components Photo no.1 Manufacturer/ Technical data and Mark(s) of Name Type / model² trademark² securement means conformity³ CONQUER **MST** T5A, 250V, Rated breaking **ELECTRONICS CO** SAT capacity 50A LTD **EVER ISLAND** T2A, 250V, Rated breaking ELECTRIC CO LTD 2010 & WALTER capacity 130A **ELECTRIC** T2A, 250V, Rated breaking **BEL FUSE INC RST** capacity 100A 7 7 Fuse (F2) cURus COOPER T2A, 250V, Rated breaking SS-5 **BUSSMANN LLC** capacity 35A DAS & SONS T2A, 250V, Rated breaking INTERNATIONAL 385T series capacity 35A LTD **SHENZHEN** T2A, 250V, Rated breaking LANSON SMT **ELECTRONICS CO** capacity 35A LTD JVR10S471K JVR14S471K JOYIN CO LTD 10N471K 14N471K EPCOS (ZHUHAI S14K300E2 FTZ) CO LTD WALSIN SR471K14D **TECHNOLOGY** SR471K10D CORP THINKING TVR10112-V **ELECTRONIC** TVR10471K INDUSTRIAL CO TVR14471K LTD SUCCESS SVR10D471K **ELECTRONICS CO** Maximum continuous voltage: SVR14D471K Varistor (MOV2) 7 8 cURus LTD 300Vac CERAMATE GNR10D471K TECHNICAL CO GND14D471K LTD **BRIGHTKING** 10D471K (SHENZHEN) CO 14D471K LTD LIEN SHUN 10D471K **ELECTRONICS CO** 14D471K LTD HONGZHI HEL-10D471K ENTERPRISES LTD | HEL-14D471K **GUANGXI NEW FUTURE** 10D471K **INFORMATION** 14D471K INDUSTRY CO LTD BOAM/HAOPUWEI/ GTM91110P-7 9 Inductor (LF1) 130℃ NR GLOBTEK/HEJIA LF1 BOAM/HAOPUWEI/ GTM91110P-7 130℃ NR 10 Inductor (LF2) GLOBTEK/HEJIA LF2 BOAM/HAOPUWEI/ GTM91110P-7 130℃ Inductor (LF3) NR 11 GLOBTEK/HEJIA LF3 BOAM/HAOPUWEI/ GTM91110P-7 130℃ 12 Inductor (LF4) NR GLOBTEK/HEJIA LF4

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4.0 Critical Components Item Manufacturer/ Technical data and Mark(s) of Name Type / model² no.1 trademark² securement means conformity³ BOAM/HAOPUWEI/ 7 PFC Inductor (L1) 405-0005 NR 13 130℃ GLOBTEK/HEJIA SHENZHEN WOER **RSFR HEAT-SHRINKABLE** RSFR-H 600V, 125℃ RSFR-HPF MATERIAL CO LTD QIFURUI QFR-h 600V, 125℃ **ELECTRONICS CO** SALIPT S-901-DONGGUAN 300 Min. 300V, 125℃ SALIPT CO LTD SALIPT S-901-600 7 14 Insulation tube **SHENZHEN** cURus WOLIDA TRADING RSFR-H 600V, 125℃ CO LTD **GUANGZHOU KAIHENG** K-2 (+) Min. 300V, 125℃ **ENTERPRISE** K-2 (CB) **GROUP CHANGYUAN ELECTRONICS CB-HFT** Min. 300V, 125℃ (SHENZHEN) CO LTD Cheng Tung Max. 1.0uF, 310Vac, 110℃, CTX Industrial Co., Ltd. type X1 or X2 Tenta Electric Max. 1.0uF, 275Vac, 100℃, MEX Industrial Co. Ltd. type X1 or X2 Ultra Tech Xiphi Max. 1.0uF, 275Vac, 110℃, HQX Enterprise Co. Ltd. type X2 Okaya Electric Max. 1.0uF, 275Vac, 100℃, RE series Industries type X2 **VISHAY Capacitors** Max. 1.0uF, 310Vac, 110℃, F1772 Belgium NV type X2 Dain Electronics Co., MPX, MEX and Max. 1.0uF, 275Vac, 100℃, X capacitor (CX1) 7 15 cURus Ltd. NPX type X2 (Optional) Max. 1.0uF, 300Vac, 110℃, Sinhua Electronics MPX (Huzhou) Co., Ltd. type X2 Shunde Da Hua Max. 1.0uF, 275Vac, 105℃, HD-MKP Electric Co., Ltd. type X2 Foshan Shunde Max. 1.0uF, 275Vac, 105℃, MKP-X2 Chuang Ge type X2 Jiangsu Xinghua Max. 1.0uF, 275Vac, 100℃, MPX Huayu Co., Ltd. Max. 1.0uF, 275Vac, 100℃, Hongzhi Enterprises **MPX** Ltd. type X2 **PANASONIC** FC series CORPORATION SMD Y-Capacitor (CY1, CY2, CY3, WALSIN Type Y2, max. 330pF, min. S242 series 7.8 CY4, CY5, CY6, cURus 16 **TECHNOLOGY** 250V, min. 85℃ S252 series CY7) (CY7 is CORP optional) MURATA MFG CO GC series LTD GA series

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4.0 Critical Components Photo no.1 Manufacturer/ Technical data and Mark(s) of Name Type / model² trademark² securement means conformity³ Ext. Cr: min. 8.0 mm; DTI: min. LITE-ON Technology LTV-817 0.6 mm; Thermal cycling test. Corporation Max. operating temp.: 115℃. Fairchild FOD817C Ext. Cr: min. 7.8 mm; DTI: min. Semiconductor FOD817A 0.6 mm; Thermal cycling test. Pte. Ltd. Max. operating temp.: 115℃ H11A817X Optocoupler (U3, 8 17 cURus U4, U5) Vishay Ext. Cr: min. 8.0 mm; DTI: min. Semiconductor TCLT1003 0.4 mm; Thermal cycling test. **GmbH** Max. operating temp.: 100℃. Ext. Cr: min. 7.7 mm; DTI: min. Everlight Electronics Co., EL817 0.5 mm; Thermal cycling test. Ltd. Max. operating temp.: 110℃. 403-0054 for 12V-14V 403-0056 for 14.1V-17V 403-0053 for Class B with insulation system Isolation GlobTek/BOAM/HAO 17.1V-21V 9 18 below, refer to illustrations No. NR transformer (T1) **PUWEI** 403-0052 for 6 for details. 21.1V-30V 403-0055 for 30.1V-40V 403-0051 for 40.1V-55V GLOBTEK INC GTX-130-TM **WUXI HAOPUWEI ELECTRONICS CO** ZT-130 9 18a Insulation system LTD Class B cURus SHAN DONG BOAM BOAM-01 ELECTRIC CO LTD Drive Transformer GlobTek/BOAM/HAO 9 19 403-0080 130℃ NR **PUWEI** (T2)TDK-EPC Type Y1, max. 1000pF, min. CD CORPORATION 250V, min. 85℃ **SUCCESS** SE Type Y1, max. 1000pF, min. **ELECTRONICS CO** SB 250V, min. 125℃ LTD MURATA MFG CO Type Y1, max. 1000pF, min. ΚX LTD 250V, min. 125℃ WALSIN Y-Capacitor Type Y1, max. 1000pF, min. 10 20 cURus **TECHNOLOGY** AΗ (CY8) 250V, min. 125℃ CORP Type Y1, max. 1000pF, min. JYA-NAY CO LTD JN 250V, min. 125℃ **HAOHUA** Type Y1, max. 1000pF, min. CT7 **ELECTRONIC CO** 250V, min. 125℃ WELSON Type Y1, max. 1000pF, min. INDUSTRIAL CO WD 250V, min. 125℃ LTD

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Dot | Name | Manufacturer/ trademark² | Type / model² | Technical data and securement means | Mark(s) of conformity³

NOTES:

- 1) Not all item numbers are indicated (called out) in the photos, as their location is obvious.
- 2) "Various" means any type, from any manufacturer that complies with the "Technical data and securement means" and meets the "Mark(s) of conformity" can be used.
- 3) Indicates specific marks to be verified, which assures the agreed level of surveillance for the component. "NR"- indicates Unlisted and only visual examination is necessary. "See 5.0" indicates Unlisted components or assemblies to be evaluated periodically refer to section 5.0 for details.

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5.0 Critical Unlisted CEC Components

No Unlisted CEC components are used in this report.

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6.0 Critical Features

<u>Recognized Component</u> - A component part, which has been previously evaluated by an accredited certification body with restrictions and must be evaluated as part of the basic product considering the restrictions as specified by the Conditions of Acceptability.

<u>Listed Component</u> - A component part, which has been previously Listed or Certified by an accredited Certification Organization with no restrictions and is used in the intended application within its ratings.

<u>Unlisted Component</u> - A part that has not been previously evaluated to the appropriate designated component standard. It may also be a Listed or Recognized component that is being used outside of its evaluated Listing or component recognition.

<u>Critical Features/Components</u> - An essential part, material, subassembly, system, software, or accessory of a product that has a direct bearing on the product's conformance to applicable requirements of the product standard.

<u>Construction Details</u> - For specific construction details, reference should be made to the photographs and descriptions. All dimensions are approximate unless specified as exact or within a tolerance. In addition to the specific construction details described in this Report, the following general requirements also apply.

- 1. Spacing Refer to illustration No(s) 2a-2d for details.
- Mechanical Assembly Components such as switches, fuseholders, connectors, wiring terminals and display lamps are mounted and prevented from shifting or rotating by the use of lockwashers, starwashers, or other mounting format that prevents turning of the component.
- 3. <u>Corrosion Protection</u> All ferrous metal parts are protected against corrosion by painting, plating or the equivalent.
- 4. <u>Accessibility of Live Parts</u> For adapter models, all uninsulated live parts in primary circuitry are housed within a non-metallic enclosure constructed with no openings and metal enclosure earthed with ventilation holes other than those specifically described in Sections 4 and 5.
- 5. <u>Grounding</u> All exposed dead-metal parts and all dead-metal parts within the enclosure that are exposed are connected to the grounding lead of the power supply cord and the equipment grounding terminal.
- 6. Polarized Connection This product is provided with a polarized power supply connection.
- 7. Internal Wiring Internal wiring is routed away from sharp or moving parts. Internal wiring leads terminating in soldered connections are made mechanically secure prior to soldering. Recognized Component separable(quick disconnect) connectors of the positive detent type, closed loop connectors, or other types specifically described in the text of this report are also acceptable as internal wiring terminals. At points where internal wiring passes through metal walls or partitions, the wiring insulation is protected against abrasion or damage by plastic bushings or grommets. All internal wiring is contained in the recognized subassembly.
- 8. <u>Schematics</u> Refer to Illustration No(s). 3, 4a & 4b for schematics & PCB layout requiring verification during Field Representative Inspection Audits.
- 9. <u>Markings</u> The product is marked as follows: brand name, model number, electrical ratings, manufacturer. Refer to Illustration No. 5 for details.
- 10 Cautionary Markings Refer to illustrations No. 5 for details.
- 11 <u>Safety Instructions</u> Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.

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7.0 Illustrations

Illustration 1 - Model list

Standard Model Number For Open Frame Version:	Output Voltage	Minimum Load*	Maximum Load no Airflow	Maximum Load with 20CFM Airflow
GT(M)91110P24012-FA(W)-S or -HIOXX or -HOXXX or -HIXXX	12V==	0,2A	12,5A	20,0A
GT(M)91110P24015-X.X-FA(W)-S or -HIOXX or -HIXXX	15V==	0,2A	10,0A	16,0A
GT(M)91110P24018-X.X-FA(W)-S or -HIOXX or -HIXXX	18V==	0,2A	8,33A	13,3A
GT(M)91110P24024-X.X-FA(W)-S or -HIOXX or -HIXXX	24V===	0,1A	6,25A	10,0A
GT(M)91110P24036-X.X-FA(W)-S or -HIOXX or -HIXXX	36V==	0,1A	4,17A	6,7A
GT(M)91110P24048-X.X-FA(W)-S or -HIOXX or -HOXXX or -HIXXX	48V===	0,1A	3,12A	5,0A
GT(M)91110P24055-X.X-FA(W)-S or -HIOXX or -HIXXX	55V===	0,1A	2,72A	4,36A

Standard Model Number For with Perforated Enclosure Version	Output Voltage	Minimum Load	Maximum Load no Airflow	Maximum Load with 20CFM Airflow
GT(M)91110P24012-CA(W)-S or -HIOXX or -HOXXX or -HIXXX	12V===	0,2A	6,7A	16,67A
GT(M)91110P24015-X.X-CA(W)-S or -HIOXX or -HOXXX or -HIXXX	15V===	0,2A	5,3A	13,38A
GT(M)91110P24018-X.X-CA(W)-S or -HIOXX or -HOXXX or -HIXXX	18V===	0,2A	4,4A	11,11A
GT(M)91110P24024-X.X-CA(W)-S or -HIOXX or -HOXXX or -HIXXX	24V===	0,1A	3,3A	8,33A
GT(M)91110P24036-X.X-CA(W)-S or -HIOXX or -HOXXX or -HIXXX	36V===	0,1A	2,2A	5,5A
GT(M)91110P24048-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX	48V===	0,1A	1,7A	4,17A
GT(M)91110P24055-X.X-CA(W)-S or -HIOXX or -HOXXX or -HIXXX	55V===	0,1A	1,4A	3,64A

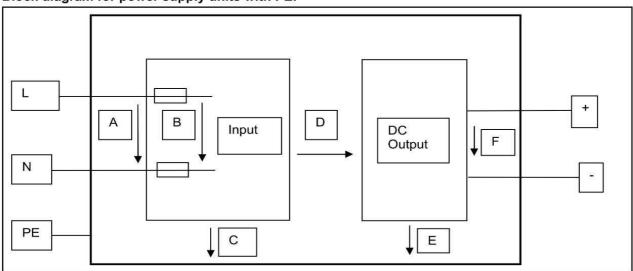
GT(M)	GLOBTEK series, means GT- or GTM
91110P	Family designator
24012	240W 12V output power and output voltage
"Z"	"Z"= "F": Open frame and "Z"= "C": Perforated enclosure
A(W)	Means A or W, "A" for airflow for 240 W load and "W" for models without protective earth (optional)
X.X	Output voltage deviation from standard model by subtracting X.X volt from standard output voltage, X.X not required to be added in model number for standard output voltage.
-S	Input header and output header connectors on board
-HIOXXX	Input and output wire harness. Where XXX can be from 000 to 500 to indicate harness length (maximum length for input and output harnesses is 500mm).
-HOXXX:	Input header connector on board and output wire harness. Where XXX can be from 000 to 500 to indicate harness length (maximum harness length for output is 500mm).
-HIXXX:	Input wire harness. Output header on board. Where XXX can be from 000 to 500 to indicate harness length (maximum harness length for input is 500mm).

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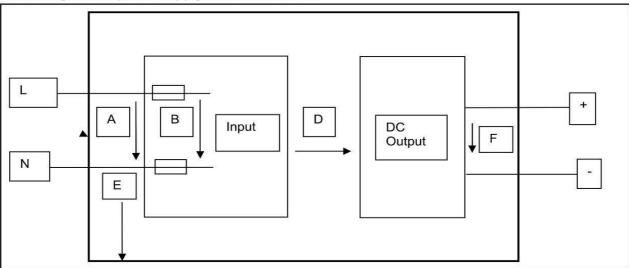
7.0 Illustrations

Illustration 2a - Insulation diagram

Block diagram for power supply units with PE:



Block diagram for power supply units without PE:



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7.0 Illustrations

Illustration 2b - TABLE: Insulation diagram (measured values)

Pollut	tion degree			: PD 2					
Overv	oltage categoi	у		: ovc	П				()
Altitu	de			: Up to	2.000 met	ers			·—·
	ional details or plied parts				lone 🔲 A	Areas for details	s)		·—·
Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Workin Vrms	g voltage Vpk	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
		P	ower su	pply unit	with protect	ctive earthi	ng (PE)		•
Α	1xMOOP	IIIb	240	340	2,5	2,0	3,7	3,7	Primary to primary before fuse (for 240 Vac)
А	1xMOOP	IIIb	320 Vdc	320 Vdc	3,4	2,0	3,7	3,7	Primary to primary before fuse (for 320 Vdc)
В	Functional	IIIb	240	340	Short circ	uit perforn	ned.		Primary to primary after fuse (for 240 Vac)
В	Functional	IIIb	320 Vdc	320 Vdc	Short circuit performed.				Primary to primary after fuse (for 320 Vdc)
С	1xMOOP	IIIb	240	340	2,5	2,0	4,0	2,5	Primary to earth (for 240 Vac)
С	1xMOOP	IIIb	320 Vdc	320 Vdc	3,4	2,0	4,0	2,5	Primary to earth (for 320 Vdc)
E	Functional	IIIb		-	Short circ	uit perforn	ned.		Secondary to earth (for 240 Vac)
E	Functional	IIIb			Short circ	uit perforn	ned.		Secondary to earth (for 320 Vdc)
F	Functional	IIIb			Short circ	uit perforn	ned.		Secondary to secondary (for 240 Vac)
F	Functional	IIIb			Short circ	uit perforn	ned.		Secondary to secondary (for 320 Vdc)
D1	2xMOOP	IIIb	240 (230,3)	392	5,0	4,0	10,7	10,7	Primary to secondary in transformer T1 (for 240 Vac)
D1	2xMOOP	IIIb	325	544	6,8	4,4	10,7	10,7	Primary to secondary in transformer T1 (for 320 Vdc)

7.0 Illustrations

Illustration 2c - TABLE: Insulation diagram (measured values) (Cont.)

D2	2xMOOP	IIIb	240	392	5,0	4,0	9,8	8,5	Primary to
			(230,3)	302	3,0	-,0	0,0	3,0	secondary in transformer T1 (for 240 Vac)
D2	2xMOOP	IIIb	325	544	6,8	4,4	9,8	8,5	Primary to secondary in transformer T1 (for 320 Vdc)
D3	2xMOOP	IIIb	240 (216,3)	400	5,0	4,0	7,4	7,4	Primary to secondary on PCB near Optical insulators (for 240 Vac)
D3	2xMOOP	IIIb	362	384	7,4	6,4	7,4	7,4	Primary to secondary on PCB near Optical insulators (for 320 Vdc)
D4	2xMOOP	IIIb	240 (230,3)	392	5,0	4,0	9,8	6,9	Primary to secondary on PCB (for 240 Vac)
D4	2xMOOP	IIIb	325	544	6,8	4,4	9,8	6,9	Primary to secondary on PCB (for 320 Vdc)
		F	Power su	ipply unit	without pr	otective ea	rthing		
A	1xMOOP	IIIb	240	340	2,5	2,0	3,7	3,7	Primary to primary before fuse (for 240 Vac)
A	1хМООР	IIIb	320 Vdc	320 Vdc	3,4	2,0	3,7	3,7	Primary to primary before fuse (for 320 Vdc)
В	Functional	IIIb	240	340	Short circuit performed.				Primary to primary after fuse (for 240 Vac)
В	Functional	IIIb	320 Vdc	320 Vdc	Short circuit performed.				Primary to primary after fuse (for 320 Vdc)
F	Functional	IIIb			Short circuit performed.				Secondary to secondary (for 240 Vac)
F	Functional	IIIb			Short circu	uit perform	ed.		Secondary to secondary (for 320 Vdc)

7.0 Illustrations

Illustration 2d - TABLE: Insulation diagram (measured values) (Cont.)

D1	2xMOOP	IIIb	240 (230,3)	392	5,0	4,0	10,7	10,7	Primary to secondary in transformer T1 (for 240 Vac)
D1	2xMOOP	IIIb	325	544	6,8	4,4	10,7	10,7	Primary to secondary in transformer T1 (for 320 Vdc)
D2	2xMOOP	IIIb	240 (230,3)	392	5,0	4,0	9,8	8,5	Primary to secondary in transformer T1 (for 240 Vac)
D2	2xMOOP	IIIb	325	544	6,8	4,4	9,8	8,5	Primary to secondary in transformer T1 (for 320 Vdc)
D3	2xMOOP	IIIb	240 (216,3)	400	5,0	4,0	7,4	7,4	Primary to secondary on PCB near Optical insulators (for 240 Vac)
D3	2xMOOP	IIIb	362	384	7,4	4,0	7,4	7,4	Primary to secondary on PCB near Optical insulators (for 320 Vdc)
D4	2xMOOP	IIIb	240 (230,3)	392	5,0	4,0	9,8	6,9	Primary to secondary on PCB (for 240 Vac)
D4	2xMOOP	IIIb	325	544	6,8	4,4	9,8	6,9	Primary to secondary on PCB (for 320 Vdc)
E	2xMOOP	IIIb	240	340	5,0	4,0	7,0	4,0	Primary to primary mounting tracks (connected to enclosure) For 240 Vac)
E	2xMOOP	IIIb	320 Vdc	320 Vdc	6,8	4,0	7,0	4,0	Primary to primary mounting tracks (connected to enclosure) For 320 Vdc)

7.0 Illustrations

Illustration 5 - Marking

The marking plates of the other models listed in this report are identical with below except model name and output parameter.



For Class I model

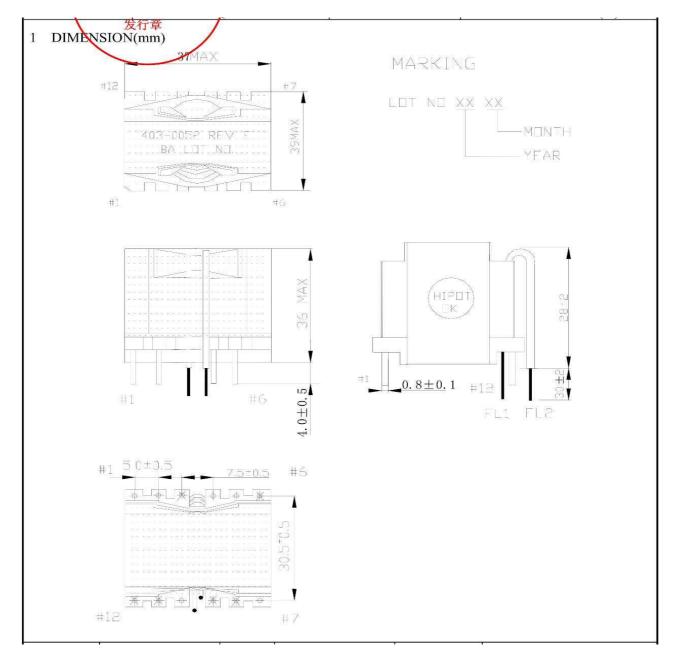


For Class II model



7.0 Illustrations

Illustration 6 - Specification for isolation transformer T1



8.0 Test Summary 2014-08-11 ~ 2014-08-19 Project No. 140800196SHA **Evaluation Period** Sample Rec. Date 11-Aug-2014 Condition Prototype Sample ID. 0140811-15-001 Test Location Building No.86, 1198 Qinzhou Road (North), Shanghai 200233, China Test Procedure **Testing Lab** Determination of the result includes consideration of measurement uncertainty from the test equipment and methods. The product was tested as indicated below with results in conformance to the relevant test criteria.

The following tests were performed:	
	ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Amendment 1; CAN/CSA-C22.2 No. 60601-1:14, Third Edition Issued: 2014/03/01 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
Test Description	Clause
Power Input	4.11
Humidity Preconditioning	5.7
Accessible Parts	5.9.2
Legibility of Markings	7.1.2
Durability of Markings	7.1.3
Plug Voltage and/or Energy	8.4.3
Working Voltage Measurement	8.5.4
Protective earthing conductor	8.6.4
Leakage Current Test terminations	8.7.4
Dielectric Strength Means	8.8.3
Ball Pressure Test	8.8.4.1
Creepage & Clearance Measurements	8.9.4
Excessive Temperature	11.1
Single Fault Conditions	13.2
Transformer Short-Circuit	15.5.1.2
Transformer Overload	15.5.1.3
Transformer Dielectric Strength	15.5.2

8.1 Signatures								
A representative sample of the product covered by this report has been evaluated and found to comply with the								
applicable requirem	applicable requirements of the standards indicated in Section 1.0.							
Completed by:	Jamie Wu	Reviewed by:	Justin Yu					
Title:	Project engineer	Title:	Reviewer					
Signature:	Jane Wu	Signature:	Jan L					

Issued: 19-Aug-2014

9.0 Correlation Page For Multiple Listings

The following products, which are identical to those identified in this report except for model number and Listee name, are authorized to bear the ETL label under provisions of the Intertek Multiple Listing Program. GlobTek, Inc. **BASIC LISTEE** 186 Veterans Dr. Northvale, NJ 07647 USA Address USA Country Product ITE/Medical Power Supply MULTIPLE LISTEE 1 None Address Country **Brand Name ASSOCIATED MANUFACTURER** Address Country MULTIPLE LISTEE 1 MODELS BASIC LISTEE MODELS MULTIPLE LISTEE 2 None Address Country **Brand Name ASSOCIATED MANUFACTURER** Address Country **MULTIPLE LISTEE 2 MODELS BASIC LISTEE MODELS** MULTIPLE LISTEE 3 None Address Country **Brand Name ASSOCIATED MANUFACTURER** Address Country **MULTIPLE LISTEE 3 MODELS BASIC LISTEE MODELS**

Issued: 19-Aug-2014

Report No. 140800196SHA-001 GlobTek, Inc.

10.0 General Information

The Applicant and Manufacturer have agreed to produce, test and label ETL Listed products in accordance with the requirements of this Report. The Manufacturer has also agreed to notify Intertek and to request authorization prior to using alternate parts, components or materials.

COMPONENTS

Components used shall be those itemized in this Intertek report covering the product, including any amendments

LISTING MARK

The ETL Listing mark applied to the products shall either be separable in form, such as labels purchased from Intertek, or on a product nameplate or other media only as specifically authorized by Intertek. Use of the mark is subject to the control of Intertek.

The mark must include the following four items:

- 1) applicable country identifiers "US" and/or "C" or "US", "C" and "EU"
- 2) the word "Listed" or "Classified" or "Recognized Component" (whichever is appropriate)
- 3) a control number issued by Intertek
- 4) a product descriptor that identifies the standards used for certification. Example:

For US standards, the words, "Conforms to" shall appear with the standard number along with the word, "Standard" or "Std." Example: "Conforms to ANSI/UL Std. XX."

For Canadian standards, the words "Certified to CAN/CSA Standard CXX No. XX." shall be used, or abbreviated, "Cert. to CAN/CSA Std. CXX No. XX."

Can be used together when both standards are used.

Note: A facsimile must be submitted to Intertek, Attn: Follow-up Services for approval prior to use. The facsimile need not have a control number. A control number will be issued after signed Certification Agreements have been received by the Follow-up Services office, approval of the facsimile of your proposed Listing Mark, satisfactory completion of the Listing Report, and scheduling of a factory assessment in your facility.

MANUFACTURING AND PRODUCTION TESTS

Manufacturing and Production Tests shall be performed as required in this Report.

FOLLOW-UP SERVICE

Periodic unannounced audits of the manufacturing facility (and any locations authorized to apply the mark) shall be scheduled by Intertek. An audit report shall be issued after each visit. Special attention will be given to the following:

- Conformance of the manufactured product to the descriptions in this Report.
- 2. Conformance of the use of the ETL mark with the requirements of this Report and the Certification Agreement.
- 3. Manufacturing changes.
- 4. Performance of specified Manufacturing and Production Tests.

In the event that the Intertek representative identifies non-conformance(s) to any provision of this Report, the Applicant shall take one or more of the following actions:

- 1. Correct the non-conformance.
- 2. Remove the ETL Mark from non-conforming product.
- 3. Contact the issuing product safety evaluation center for instructions.

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Issued: 19-Aug-2014 GlobTek, Inc. Revised: None

10.1 Evaluation of Unlisted Components

Because Unlisted Components are uncontrolled, and they do not fall under a third party follow up program, Intertek may require these components to be tested and/or evaluated at least once annually, more often for certain components, as part of the independent certification process. The Unlisted Components in Section 5.0 require testing and/or evaluation as indicated.

Note to Intertek Follow Up Inspector: The Component Evaluation Center, CEC, will notify you in writing when these components must be selected and sent to the CEC for re-evaluation

> Ship the samples to: Intertek Testing Services Shanghai Limited **ETL Component Evaluation Center** Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233, China

Attn: Ms. Dansy Xu Sample Disposition: Due to the destructive nature of the testing, all samples will be discarded at the conclusion of testing unless, the manufacturer specifically requests the return of the samples. The request for return must accompany the initial component shipment.

Issued: 19-Aug-2014 GlobTek, Inc. Revised: None

11.0 Manufacturing and Production Tests

The manufacturer agrees to conduct the following Manufacturing and Production Tests as specified:

Required Tests

Dielectric Voltage Withstand Test

Grounding Continuity Test

11.1 Dielectric Voltage Withstand Test

Method

One hundred percent of production of the products covered by this Report shall be subjected to a routine production line dielectric withstand test.

The test shall be conducted on products, which are fully assembled. Prior to applying the test potential, all switches, contactors, relays, etc., should be closed so that all primary circuits are energized by the test potential. If all primary circuits cannot be tested at one time, then separate applications of the test potential shall be made.

The test voltage specified below shall be applied between primary circuits and accessible dead-metal parts. The test voltage may be gradually increased to the specified value but must be maintained at the specified value for one second or one minute as required.

Test Equipment

The test equipment shall incorporate a transformer with an essentially sinusoidal output, a means to indicate the applied test potential, and an audible and/or visual indicator of dielectric breakdown.

The test equipment shall incorporate a voltmeter in the output circuit to indicate directly the applied test potential if the rated output of the test equipment is less than 500VA.

If the rated output of the test equipment is 500VA or more, the applied test potential may be indicated by either:

- 1 a voltmeter in the primary circuit;
- 2 a selector switch marked to indicate the test potential; or
- 3 a marking in a readily visible location to indicate the test potential for test equipment having a single test potential output.

In cases 2 and 3, the test equipment shall include a lamp or other visual means to indicate that the test potential is present at the test equipment output. All test equipment shall be maintained in current calibration.

Products Requiring Dielectric Voltage Withstand Test:							
<u>Product</u>	Test Voltage	Test Time					
Between L/N and PE terminal for Class I models only	1500Vac	1 s					
Between L/N and secondary output for Class II models only	3000Vac	1 s					

11.1 Dielectric Voltage Withstand Test

Each product listed below shall be subjected to a test to determine that there is continuity between accessible dead-metal parts of the product and the grounding pin or blade of the attachment plug.

If all accessible dead metal is connected, only a single test need be performed. A visual or audible device (ohmmeter, buzzer, etc.) may be used to indicate grounding continuity.

Products Requiring Grounding Continuity Test:

Class I models covered by this Report.

The following changes are in compliance with the declaration of Section 8.1:

Date/
Proj # Site ID

Reviewer

Section Item Description of Change
None

None

Issued: 19-Aug-2014